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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,119	03/19/2001	Michael J. O'Connor	MICRU: 56212	2506

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EXAMINER	
FARAH, AHMED M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/813,119	Applicant(s) O'Connoor et al.
	Examiner A. Farah	Art Unit 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 3, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-23* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *8*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-3, 5-10, 12-14, 16-21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. U.S. Pat. No. 6,063,080.

As to claims 1-3, 6, 8, 12-14 and 17, Nelson et al. disclose a variable stiffness heating catheter 12 for use in interventional vascular therapy, comprising:

a heating catheter shaft (hollow shaft **50**; see Fig. 5) having a proximal end and a distal end **14**, said heating catheter shaft including at least one electrically conductive element (flexible, tabular electrode **18**, which is formed of shape memory metal, see Col. 7, lines 26-30); and

reinforcing tubes (coaxial tubes **40**, **52** and **54**; see Fig. 5 and Col. 6, lines 1-34) attached to the heating catheter shaft (hallow shaft **50** which incloses RF electrode **18**), the heating catheter shaft extending through the reinforcing tubes (heating electrode **18** and inclosing shaft **50** extend through hollow tubes **40**, **52** and **54**), wherein at least one of said reinforcing tubes having a surface defining a plurality of apertures (micro-apertures **84**) to provide variation in stiffness along the length of the heating catheter shaft (see Fig. 4 and Col. 7, lines 49-52).

As to claims 5, 7, 16 and 18, the outer surface of at least one of the reinforcing tube (coaxial tube **40**) has a configuration selected from the set consisting of: a continuous tube having a constant diameter, a continuous tube having a continually tapered diameter, a continuous tube having at least a portion of which has a tapered diameter, a series of tubes of varying degrees of flexibility which are fixed connected together in a coaxial, end-to-end manner," and any combination thereof. See Col. 6, lines 10-28.

As to claims 9 and 20, the outer tube of their catheter is constructed of a nylon (Merriam Webster's Collegiate Dictionary defines nylon as any of a family of high-strength, resilient synthetic polymers, the molecules of which contain the recurring amide group CONH). See Col.4, lines 59-62.

As to claims 10 and 21, Fig. 3 of Nelson et al. clearly shows that the catheter body **12** is sealed by pressure fit or heat shrinking (Col. 6, lines 63-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 4 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. in view of Mueller U.S. Pat. No. 4,801,297.

Although Nelson et al., described above, form lateral slits (micro-apertures 84) on the outer surface of their catheter to increase its flexibility, they fail to teach the use of helical slits as presently claimed.

However, Mueller teaches a flexible medical catheter **10** having a plurality of axial slits **20** and a plurality of helical slits **28** disposed on the outer surface of the catheter body **12** so as to increase the flexibility of the catheter tip **24** (Fig. 1; Col. 1, lines 64-67; and Col. 2, lines 15-20). The increase in flexibility enables the catheter to bend very easily within a body lumen thereby reducing the risk of arterial wall puncture and damage.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Nelson et al. with Mueller and form helical and/or axial slits on the outer surface of the catheter body in order to increase its flexibility. Since these are not critical, provided no unexpected results, the helical and/or axial slits would have been an

equivalent alternative pressure release to the lateral slits of Nelson et al.

4. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. in view of Nardella U.S. Pat. No. 5,334,193. (AF) 11/13/02

Although Nelson et al., described above, teach that the outer body of their catheter is made of polymer (nylon), their polymer is not selected from the group consisting of polyethylene, polytetrafluoroethylene, polyetherethulketone or polyphenylenesulfide as presently claimed.

However, Nardella discloses an electrosurgical catheter manufactured of flexible, biocompatible polymer, such as polyolefins, nylons, or polytetrafluoroethylene. He further teaches that the use, compatibility, and/or interchangeability of the different polymers are well known in the art of manufacturing medical catheters (Col. 5, lines 12-21). Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Nelson et al. in view of Nardella to have a catheter body manufactured of polytetrafluoroethylene polymer. Furthermore, it is known in the art that the flexible polymeric materials such, polyethylene, polyvinylcholoride, or polytetrafluoroethylene behave as heat resistant when an electric potential is applied across them.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 6,251,129 B1 to Dobak, III et al. teaches a flexible heating catheter comprising at least one electrically conductive element **14** and a reinforcing tube **42** manufactured form polytetrafluoroethylene polymer. See Col. 10, lines 49-52; and Col. 13, lines 4-25.

U.S. Patent 5,713,864 to Verkaart disclose a flexible, integral polymer resistance heated conduit that is particularly suitable for use with catheters. See Col. 2, line 65 to Col. 3, line 18.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax number for the Examiner is (703) 746-3368.

A. M. Farah

Patent Examiner

Art Unit 3739

November 13, 2002

Linda C. M. Dvorak

Supervisory Patent Examiner